



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
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August 14, 2002

WARNING LETTER NO. 2002-NOL-40

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. James B. Wheat, President
Mrs. Wheat's Fabulous Foods, Inc.
4532 Marais Street
New Orleans, Louisiana 70117

Dear Mr. Wheat:

United States Food and Drug Administration (FDA) investigators inspected your food manufacturing facility, located at 4532 Marais Street, New Orleans, Louisiana, during April 30 – May 2, 2002. During the inspection, our investigators documented numerous insanitary conditions, which caused the ingredients and finished food products manufactured, packed, and/or held at your facility to become adulterated. The adulterated ingredients and finished food products are in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act, in that they have been held under insanitary conditions whereby they may have become contaminated with filth.

The deviations are as follows:

You have not taken effective measures to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. For example, vermin and evidence of apparent vermin activity was observed in, on, and near food products stored in your facility, on food processing equipment, and in your food processing areas. This evidence included:

- Rodent excreta pellets on food products and food processing equipment;
- Apparent rodent gnawing on bags of flour;
- Two rodent gnawed holes, measuring 2" x 3" and 1½" x 1½", at the base of the walls in the USDA inspector's office;
- One rodent gnawed hole, measuring 1" x 9", at the junction between the floor and wall of the production area;
- Live roaches, too numerous to count, on bags of raw materials and in food processing areas; and,

- Live ants, too numerous to count, in the doorway between the boiler room and the freezer.

In addition, our investigator documented conditions associated with the construction, design, and maintenance of your facility that facilitate unsanitary operations. For example:

- Sinks in the production room and cleaning rooms drain directly onto the floor, and furthermore, water leaked from the sink in the packaging room;
- Water leaked from the base of toilets within the restrooms;
- Floors in the production rooms, packing room, and an employee break room were pitted, allowing water to accumulate in those areas;
- Raw materials, including bags of spices and flour, were stored directly against the walls;
- Bottles of bleach were stored above pallets of flour; and,
- An opened exhaust fan allows entry directly to the cooking room from outside the facility.

Food processing equipment is not maintained in a sanitary condition to prevent food from becoming adulterated. For example:

- The interior of the cooking kettles were heavily pitted;
- Food preparation utensils were stored, as clean, in plastic tubs with dirty water;
- Blades of the horizontal mixer were rusted;
- Rollers of the dough press were rusted; and,
- Conveyor belt of the pastry presser was frayed and split.

You have failed to keep the grounds about your processing facility in a condition that will minimize the potential for becoming an attractant and harborage or breeding place for pests, and protect against contamination of your products. For example:

- A large pool of water (4' x 4') was observed just outside the men's restroom;
- Trash was observed underneath shelving in the storage/receiving area;
- Unused equipment and boxes are stored outside and adjacent to the facility; and,
- A pile of shrubbery is stored against the building.

The above listed violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that your facility is operated in a sanitary manner.

You should take prompt action to correct these violations and to prevent the recurrence of similar violations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions may include seizure, injunction, and/or prosecution.

We are aware that on May 1, 2002, you destroyed the following raw materials found contaminated with apparent rodent urine stains or other types of apparent rodent excrement on the bags at the request of Mr. Andrew Messina, Sanitarian, Louisiana State Food and Drug Unit: 7/50 lb. bags of Sno Prince Flour; 12/13 lb. bags of #1 Deep South Blenders Meat Pie Seasoning; and, 4/16.38 lb. bags of # 2 Deep South Blenders Meat Pie Seasoning.

At the conclusion of the inspection, you were presented with a list of observations of apparent insanitary conditions on a Form FDA 483, Inspectional Observations. At that time, you presented the FDA investigator with a list of intended facility corrections in the form of a handwritten list of physical problems with your facility. We have reviewed this list and have determined that it does not adequately address how the insanitary conditions in your facility are to be corrected or the underlying causes of the insanitary conditions.

You should notify this office, in writing, within 15 days of receipt of this letter, of the steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 days, please state the reason for the delay and the time by which the corrections will be completed.

Your response should be directed to Mark W. Rivero, Compliance Officer, U.S. Food and Drug Administration, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127. Should you have any questions concerning the contents of this letter, you may contact Mr. Rivero at (504) 253-4519.

Sincerely,



Carl E. Draper
District Director
New Orleans District

Enclosure: Form FDA 483